

(19)

Europäisches Patentamt
European Patent Office
Office européen des brevets



(11)

EP 1 084 720 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:
21.03.2001 Bulletin 2001/12

(51) Int Cl.7: **A61L 31/04**

(21) Application number: **00308008.2**

(22) Date of filing: **14.09.2000**

(84) Designated Contracting States:
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE**
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **15.09.1999 US 396418**

(71) Applicant: **ED. GEISTLICH SÖHNE AG FÜR
CHEMISCHE INDUSTRIE
6110 Wolhusen (CH)**

(72) Inventors:
• **Geistlich, Peter**
6362 Stansstad (CH)
• **Boyne, Philip J.**
Loma Linda, CA 92354 (US)
• **Schlösser, Lothar**
64297 Darmstadt (DE)

(74) Representative: **Pett, Christopher Phineas**
Frank B. Dehn & Co.,
European Patent Attorneys,
179 Queen Victoria Street
London EC4V 4EL (GB)

(54) **Use of a collagen membrane in a method of protecting spinal area**

(57) There is described the use of a sheet of collagen membrane material for the protection of the spinal

cord during or after surgery and a method for using such a membrane in the protection of the spinal area of a patient during and/or after surgery.

EP 1 084 720 A1

BEST AVAILABLE COPY

Description**BACKGROUND OF THE INVENTION****FIELD OF THE INVENTION**

[0001] The present invention relates to the field of spinal surgery, including protecting a spinal area of a patient during or after surgery.

DESCRIPTION OF THE BACKGROUND ART

[0002] There are numerous spinal surgeries performed each year to treat disc injuries, to repair, remove or fuse vertebrae, or combinations thereof. During such surgeries, it is desirable to protect the spinal cord and the dura sheath surrounding the spinal cord from injury. Spinal surgeries often also involve insert of bone graft material to repair or replace damaged vertebrae. During the subsequent healing process, it is desirable to protect the spinal area from ingrowth of connective tissue and undesired cells which might interfere with proper healing.

[0003] There remains a need in the art for new methods and materials to assist in spinal surgery or for protecting spinal areas of a patient during and after surgery.

SUMMARY OF THE INVENTION

[0004] In accordance with one aspect of the present invention, a method of protecting a spinal area of a patient comprises positioning a sheet of collagen membrane material so as to surround at least a portion of a patient's spinal cord. The invention further relates to the use of a collagen membrane material as a surgical article for use in spinal surgery. This may either be to assist in vertebral fusion and/or for protecting the spinal cord during and/or after surgery.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] Fig. 1 is a sectional schematic view showing a spinal cord surrounded by a sheet of collagen membrane material in accordance with one embodiment of the present invention.

[0006] Fig. 2 is a schematic plan view in partial cross-section showing a second embodiment of the present invention wherein a first sheet of collagen membrane material is immediately adjacent a patient's spinal cord, and a second sheet of collagen membrane material is positioned outside a patient's vertebrae, spinal disc and inserted vertebrae implant material.

[0007] Fig. 3 is a side elevation schematic view showing a single-layered membrane for use in accordance with the present invention.

[0008] Fig. 4 is a side elevation schematic view showing a double-layer membrane for use in accordance with the present invention.

[0009] Fig. 5 is a side elevation schematic view showing a triple-layer membrane for use in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0010] The present invention includes a method of protecting areas of the spinal cord and column during and after spinal surgery and a collagen membrane as an article for use in such a method.

[0011] In accordance with one embodiment, during spinal surgery in which the dura sheath surrounding the spinal cord is exposed, a sheet of collagen membrane material 10 is positioned adjacent the dura sheath 12 surrounding a patient's spinal cord 14 so as to protect the dura sheath 12. See Figs. 1 and 2.

[0012] In accordance with one embodiment, the collagen membrane material is comprised of at least one barrier layer having at least one smooth face 16 so as to inhibit cell adhesion thereon and act as a barrier to prevent passage of cells therethrough. See Fig. 3. In accordance with this embodiment, the barrier layer further has a fibrous face 18 opposite the smooth face 16, the fibrous face allowing cell growth thereon. In preferred embodiments, the barrier layer is predominantly collagen I, collagen III or a mixture thereof. One suitable material is Biogide®, from Ed. Geistlich Söhne AG für Chemische Industrie, the assignee of the present invention. The Biogide® material is described in U.S. Patent No. 5,837,278, incorporated herein by reference.

[0013] Fig. 4 shows a second type of membrane which may be used in accordance with the present invention. This membrane includes a barrier layer 15 as shown in Fig. 3, and further includes a matrix layer 20 predominantly of collagen II having an open sponge-like texture. A collagen membrane as shown in Fig. 4 is described in PCT application no. PCT/GB98/02976, filed October 5, 1998, designating the U.S. and claiming priority from U.K. patent application no. 9721585.9, filed October 10, 1997, incorporated herein by reference.

[0014] In one preferred embodiment, a collagen membrane material as shown in Fig. 4 is utilized, wherein the barrier layer 15, the matrix layer 20, or both are impregnated with a glycosaminoglycan. Examples of suitable glycosaminoglycans include hyaluronic acid, chondroitin 6-sulphate, keratin sulphate or dermatan sulphate.

[0015] Fig. 5 shows still another type of membrane suitable for use in accordance with the present invention. The membrane of Fig. 5 includes two barrier layers 15, between which is sandwiched a resorbable polymer layer. In preferred embodiments, the polymer is a polylactic acid polymer. Examples of membranes as shown in Fig. 5 are described in U.K. patent application no. 9906711.8, filed March 23, 1999.

[0016] Referring back to Fig. 2, in accordance with another embodiment of the present invention, a sheet 10' of collagen membrane material is positioned so as to

surround at least a portion of a vertebrae 22 surrounding the spinal chord 14. In certain surgeries, a vertebrae implant material 24 such as resorbable bone mineral may be positioned between two vertebrae 22a and 22b so as to facilitate fusion of vertebrae 22a and 22b. In accordance with this aspect, the invention encompasses a sheet of collagen material 10' so as to surround at least a portion of the vertebrae implant material 24. One suitable vertebrae implant material is Bio-Oss® from Ed. Geistlich söhne AG Für Chemische Industrie, the assignee of the present invention. Bio-Oss® is described in U.S. Patent Nos. 5,167,961 and 5,417,975 incorporated herein by reference. Another suitable vertebrae implant material is Bio-Oss Collagen® from Ed. Geistlich Söhne AG Für Chemische Industrie, which is resorbable bone mineral in a collagen matrix. Bio-Oss Collagen® is described in U.S. Patent No. 5,573,771 incorporated herein by reference. The present invention also is applicable to other bone graft methods, such as the "cage technique", in which a net of titanium enclosing bone graft material is inserted between vertebrae.

[0017] In accordance with these and other embodiments, a sheet of collagen membrane material can protect against ingrowth of any connective tissue and other cells from outside adjacent bone material, which might interfere with osteocytes and other bone-regenerating cells from fully incorporating the spinal implant material into the spinal column for maximum strength and healing.

[0018] The method of the present invention also encompasses positioning a sheet of collagen membrane material 10' so as to surround at least a portion of a spinal disc 26 surrounding spinal chord 14 as shown in Fig. 2. In the embodiment shown in Fig. 2, the dura 12 has been surrounded by a collagen membrane 10 in accordance with the present invention, and in addition thereto, a second collagen membrane 10' has been wrapped around vertebrae 22a and 22b, as well as disc 26 and vertebrae implant material 24 for protection thereof. The present invention is thus capable of protecting the spinal chord dura from physical injury during surgery, and the barrier layer of membrane 10' protects the surgical site from ingrowth of unwanted cells during the healing process when membrane 10' is wrapped around the spinal column as shown in Fig. 2. The collagen membrane material 10, 10' is gradually resorbed into the patient's body, avoiding any necessity of having to surgically remove the membranes after healing.

[0019] While the invention has been described in detail, it is not intended that the description and accompanying drawings be interpreted in a limiting sense.

Claims

1. The use of a sheet of collagen membrane material in the preparation of a surgical article for use in or after spinal surgery.
2. The use of claim 1 wherein said collagen membrane material is comprised of at least one barrier layer having at least one smooth face so as to inhibit cell adhesion thereon and act as a barrier to prevent passage of cells therethrough.
3. The use of claim 1 or claim 2 wherein said barrier layer further has a fibrous face opposite said smooth face, said fibrous face allowing cell growth thereon.
4. The use of any of claims 1 to 3 wherein said barrier layer is predominantly collagen I, collagen III or a mixture thereof.
5. The use of claim 4 wherein said collagen membrane further comprises a matrix layer predominantly of collagen II having an open sponge-like texture.
6. The use of any of claims 2 to 5 wherein said barrier layer, said matrix layer or both, are impregnated with glycosaminoglycan.
7. The use of claim 6 wherein the glycosaminoglycan is hyaluronic acid, chondroitin 6-sulphate, keratin sulphate or dermatan sulphate.
8. The use of any of claims 2 to 7 wherein said membrane material further comprises a second barrier layer, with a resorbable polymer layer sandwiched between the barrier layers.
9. The use of claim 8 wherein said polymer is a polylactic acid polymer.
10. The use as claimed in any of claims 1 to 9 wherein the spinal surgery includes vertebral fusion and/or insertion of a vertebra implant material.
11. The use of any of claims 1 to 10 wherein said sheet is adapted to be positioned during protection of the spinal cord adjacent a dura sheath of said spinal cord so as to protect said dura sheath.
12. The use as claimed in claim 11 in association with the insertion of a vertebrae implant material outside said sheath adjacent said dura sheath.
13. The use of any of claims 1 to 12 wherein said sheet is adapted to surround at least a portion of a vertebrae surrounding said spinal cord.
14. The use of any of claims 1 to 13 wherein said sheet is adapted to be positioned so as to surround at least a portion of a spinal disc surrounding said spinal cord.
15. A collagen membrane material in sheet form for use

in surgery involving the spinal column or spinal cord.

5

10

15

20

25

30

35

40

45

50

55

4

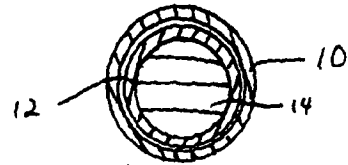


Fig. 1

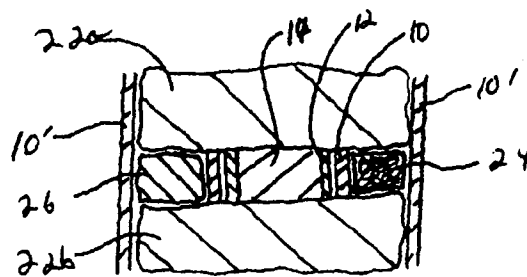


Fig. 2

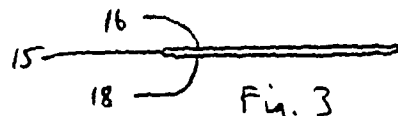


Fig. 3

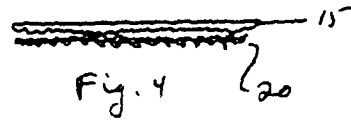


Fig. 4



Fig. 5

EP 1 084 720 A1

European Patent
Office

EUROPEAN SEARCH REPORT

Application Number

EP 00 30 8008

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	WO 95 18638 A (GEISTLICH SOEHNE AG; GEISTLICH PETER (CH); ECKMAYER ZDENEK (DE); H) 13 July 1995 (1995-07-13)	15	A61L31/04
Y	* page 1, paragraph 2 *	1-14	
D	* page 2, paragraphs 4,5 *		
	& US 5 837 278 A (GEISTLICH PETER ET AL.) 17 November 1998 (1998-11-17)		
Y	HIRAIZUMI Y ET AL.: "Application of Polyvinyl Alcohol Hydrogel Membrane as Anti-adhesive Interposition After Spinal Surgery" SPINE, vol. 20, no. 21, 1 November 1995 (1995-11-01), pages 2272-2277, XP000974659	1-14	
	* page 2272, right-hand column, last paragraph - page 2273, left-hand column, paragraph 3 *		
A	WO 99 19005 A (GEISTLICH SOEHNE AG; GEISTLICH PETER (CH); ECKMAYER ZDENEK (DE); S) 22 April 1999 (1999-04-22)	1,4-9	TECHNICAL FIELDS SEARCHED (Int.Cl.7) A61L
	* page 2, line 21 - line 29 *		
	* page 4, line 23 - line 28 *		
	* page 5, line 36 - page 6, line 8 *		
	* page 7, line 14 - line 16 *		
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 17 January 2001	Examiner Heck, G
CATEGORY OF CITED DOCUMENTS X: particularly relevant if taken alone Y: particularly relevant if combined with another document of the same category A: technological background O: non-written disclosure P: intermediate document		T: theory or principle underlying the invention E: earlier patent document, but published on, or after the filing date D: document cited in the application L: document cited for other reasons &: member of the same patent family, corresponding document	

EPO FORM 1603 03/92 (P4/C01)

EP 1 084 720 A1

ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.

EP 00 30 8008

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

17-01-2001

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9518638 A	13-07-1995	CA 2180659 A	13-07-1995
		EP 0738161 A	23-10-1996
		JP 9507144 T	22-07-1997
		US 5837278 A	17-11-1998
WO 9919005 A	22-04-1999	EP 1023091 A	02-08-2000

EPO FORM P0452

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82